VALUE IN HEALTH REGIONAL ISSUES 2 (2013) 331–332

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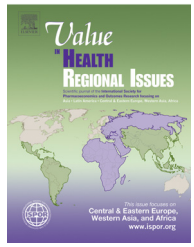

LETTERS TO THE EDITOR

Response to "Potential Regulatory and Commercial Environment for Biosimilars in Latin America" by Azevedo et al.

I refer to the article titled "Potential regulatory and commercial environment for biosimilars in Latin America" written by Azevedo et al., published in *Value in Health Regional Issues* 1 (2012):228–34, which contains incorrect information about biosimilars' regulation and market environment in Mexico.

It must be emphasized that until now there have been no reported cases of anaphylactic shock related to Kikuzubam in Mexico or elsewhere and that there are no safety concerns with the product. The authors based their assertion on a newspaper article that consisted of an interview with a competitor's executive at its facility in Palo Alto, CA [1]. The mentioned rash and anaphylactic shock cases never existed and were never reported.

This is why Probiomed would like to explain to your distinguished readers that there are no Kikuzubam's safety data concerns published by any scientific journal or official communication from the Mexican health authorities supporting those claims against the product.

In addition, we identified that the Mexican current situation described by Sandorff et al. has several inaccuracies regarding the regulatory framework for biotechnology drugs. The authors omit to mention that Mexican health authorities issued a decree amending and adding various provisions of the regulation of health products in October 2011 [2].

Although Sandorff et al. mentioned that phase III comparative trials may not be required for biosimilars and the main factor influencing the decision will be the product type, the regulation cited above describes how biotechnology products require pharmacokinetics, pharmacodynamics, safety, and efficacy clinical trials. Kikuzubam complied with all these requirements.

The safety and scientific requirements endorsed in the Emergency Mexican Official Standard NOM-EM-001-SSA1-2012 for biotechnology drugs and biopharmaceuticals published in September 2012 include Good Manufacturing Practices compliance, technical and scientific safety, efficacy and quality proof, labeling, and requirements for biocomparability studies and active pharmacovigilance [3].

Mexican health authorities' initiatives confirm that the new biosimilar registration pathway has been designed to align the Mexican regulatory framework with International Conference of Harmonization requirements, instead of just pretending to increase access to biosimilars as Sandorff et al. claimed.

Finally, it is a known fact that biotechnology generic drugs (as they were called before the terms "biosimilars" or "biocomparables" were coined) have been in the Mexican health system for over 20 years.

Probiomed has developed such products since 1996; the portfolio includes recombinant proteins, cytokines, hormones, recombinant vaccines, monoclonal antibodies, and fusion proteins. In approximately 15 years, Probiomed has supplied more than 76 million doses of biotechnology products to health institutions, health care professionals, and patients in Mexico and several countries, without receiving any safety or efficacy complains.

More than 15 million patients have been exposed to Probiomed's biotechnology generic drugs as detailed in Table 1.

We appreciate and thank you for giving us the opportunity to make these clarifications.

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http://dx.doi.org/10.1016/j.vhri.2013.05.007

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Table 1 – Patients treated with biosimilars manufactured by Probiomed.

Probiomed biosimilar name	A P I	Original brand/ laboratory	Approval year	Units distributed per year				Total units	Treated patients†
				2010*	2011	2012	2013		
Gramal	Molgramostim	Leucomax/Sch-P	1996	157,633	3,652	227	3,654	165,166	23,595
Proquiferón	Alfa 2a IFN	Roferón/Roche	1996	169,492	–	–	–	169,492	1,412
Urifrón	Alfa 2b IFN	Intrón-A/Sch-P	1997	977,341	170,035	183,316	49,745	1,380,437	11,504
Bioyetin	Eritropoyetin (rHu-EPO)	Recormón/Roche	1998	12,764,557	2,198,892	2,317,365	4,887,978	22,168,792	213,161
Probivac pediatric	HBv Vaccine	Engerix-B/Glaxo	2000	4,532,144	3,875,000	3,927,069	7,500,000	19,834,213	6,611,404
Probivac adult	HBv Vaccine	Engerix-B/Glaxo	2000	17,030,081	4,969,950	1,296,456	2,500,000	25,796,487	8,598,829
Filatil	Filgrastim	Neupogen/Roche	2001	436,274	79,072	84,133	317,639	917,118	131,017
Protophin	Somatropin	Humatrope/Lilly	2001	130,294	47,424	44,016	18,000	239,734	7,882
Glinux	Insulin	Humulin/Lilly	2001	3,709,686	224,231	55,330	23,400	4,012,647	131,923
Uribeta	Beta 1b IFN 8 MUI	Betaferon/Bayer	2002	360,720	106,083	121,742	154,669	743,214	4,764
Emaxem	Beta 1a IFN 12 MUI	Rebif/Merck-Se	2004	188,442	13,922	14,544	16,391	233,299	1,496
Jumtab	Beta 1a IFN 6 MUI	Avonex/Bayer	2006	111,244	20,883	25,852	13,575	171,554	3,299
Kikuzubam	Rituximab	Mabthera/Roche	2010	–	12,685	40,593	63,461	116,739	7,708
Infinitam	Etanercept	Enbrel/W-Pfizer	2012	–	–	–	248,000	248,000	2,583
								Total biosimilar units	**76,166,892**
								Total patients treated	**15,750,577**

Note. For more than 15 years, Probiomed has offered more than 76 million doses of biosimilar products for the treatment of more than 15 million patients in Mexico and in the global market. Probiomed has never received a report of immunogenicity or adverse events on its biosimilars, different from those reported by the original product. All Probiomed products are under strict pharmacovigilance programs.

* From year of registration up to 2010.

† The number of patients was calculated according to current posological schemes.